Remarks

The above Amendments and these Remarks are in reply to the Office Action mailed July 5, 2006. A Petition for Extension of Time to Respond is submitted herewith, together with the appropriate fee.

Rejections Under 35 U.S.C. §112

Claims 30-35, 49-51 and 56-58 stand rejected under 35 U.S.C. §112, first paragraph for lack of enablement of "an analog thereof, a functionally equivalent ligand, or a functionally equivalent endogenous ligand."

Applicants have removed these limitations from claim 30, and now believe that this rejection is overcome.

Applicants have amended certain claims to specify "secondary neuroprotective agents." With the explicit disclosure of such specific agents, Applicants submit that the claims meet the enablement requirement.

Claims 30-35, 49-51 and 56-58 stand rejected under 35 U.S.C. §112, first paragraph for failing to meet the written description requirement. As noted above, Applicants have amended the claims to particularly point out specific compositions and uses, and believe that the claims meet the written description requirement.

Rejections Under 35 U.S.C. §102

Burman

Clauns 30-32 and 34-35 stand rejected under 35 U.S.C. §102(b) as anticipated by Burman et al., ("Burman").

Burman disclosed administering growth hormone (GH) to growth hormone-deficient patients, but not in patients suffering from decreased cerebral blood flow, such as can be found in patients suffering from hypoxia, ischemia, stroke or other such disorders. Further, Applicants submit that Burman does not show transport of GH to those cells at risk of degeneration or death as disclosed in the instant application.

Thus, Applicants respectfully submit that the relevant "inherent property" of gaining access to cells destined to degenerate or die as a result of hypoxia or ischemia is not "necessarily present" in the use of GH as disclosed in Burman.

Nyberg

Claims 30-32 and 34-35 stand rejected under 35 U.S.C. §102(b) as anticipated by Nyberg et al. ("Nyberg").

As with Burman discussed above, Nyberg discloses administering GH to patients with GH-deficiencies, but not to patients having decreased cerebral blood flow. Further, Applicants submit that Nyberg does not show transport of GH to those cells at risk of degeneration or death as disclosed in the instant application.

Thus, Applicants respectfully submit that the relevant "inherent property" of gaining access to cells destined to degenerate or die as a result of hypoxia or ischemia is not "necessarily present" in the use of GH as disclosed in Nyberg.

Golab

Claims 30-32 and 34-35 stand rejected under 35 U.S.C. §102(b) as anticipated by Golab et al. ("Golab"). Applicants note that the Examiner indicated in the Office Action that no translation of Golab is available, and that a translation would be supplied to the Applicants. However, as of this date, no translation of Golab has been received from the Examiner, and that the remarks herein do not reflect an official translation of Golab. Applicants do not necessarily agree with the Examiner's characterization of Golab. Nonetheless, in the interest of moving this case forward, Applicants provide the following comments based upon the Examiner's representations of Golab.

Applicants submit that Golab cannot anticipate the instant claims.

First, the two anecdotal cases mentioned and the fact that GH was administered does not rise to the level of an enabled disclosure. Applicants submit that at best, Golab as cited provides an "invitation to experiment" and does not provide an enabling disclosure of a "neuroprotective effect..." of GH.

Next, it is not clear from the descriptions of Golab that the effect of GH was could not have been due to a simple metabolic effect of GH, for example, to increase the synthesis of proteins. Thus, a neuroprotective effect of GH is not "necessarily present" based on the limited disclosure of Golab.

Finally, it is not clear from Golab that the observed recovery of functional movement in the two patients was due to a "neuroprotective effect of protecting or rescuing neurons destined to degenerate or die as a result of hypoxia or ischemia effect of protecting or rescuing neurons destined to degenerate or die" as in Applicants' claims. Thus, the newly discovered "neuroprotective effect" of GH is not anticipated by Golab.

Double Patenting

Claims 30-35, 49-51 and 58 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. patent No: 6,187,906 (the "906 patent") in view of Golab.

Applicants respectfully disagree that the combination of the 906 patent and Golab renders the instant claims obvious.

First, Applicants have amended the claims (including independent Claim 30) to delete the functional language "an analog thereof, or a functionally equivalent ligand." Thus, there is no basis for the allegation that use of GPE is "equivalent" to GH in the instant claims. Applicants are not claiming that GPE is "an analog or functionally equivalent ligand" and therefore, there is no overlap in the claims.

Further, as noted above, Applicants submit that Golab does not teach or suggest a neuroprotective role of GH. Rather, Applicants submit that Golab might provide an "invitation to experiment" to see if GH might be a neuroprotective agent. This standard: "obvious to try" has been rejected by the courts and is not the proper standard of obviousness. Thus, Golab cannot provide a grounds for obviousness of the instant claims.

The 906 patent discloses the use of a completely different compound, GPE, as a neuroprotective agent. The Examiner has not provided a "reasoned statement" supporting the idea that successful use of GPE as a neuroprotective agent as in the 906 patent, would be viewed by one of ordinary skill in the art as teaching that GH would also be neuroprotective.

Interference

As noted above and as is apparent from the claims as amended, Applicants submit that there is no basis for any interference proceeding, as the claims of the 906 patent and the instant claims do not overlap.

With reference to claim 50, Applicants submit that claims 1-11 of the 906 patent do not include use of GH as a neuroprotective agent. The instant claim 50 discloses GPE as a "secondary neuroprotective agent." Thus, Applicants respectfully submit that the claims do not overlap and that no interference exists.

Rejections Under 35 U.S.C. §103

Claims 30-35, 49-51 and 56-58 stand rejected under 35 U.S.C. §103(a) as obvious over the combination of the 906 patent and Golab.

As discussed above under the paragraph "Double Patenting," Applicants submit that the combination of the 906 patent and Golab does not render the instant claim obvious.

First, Applicants have amended the claims (including independent Claim 30) to delete the functional language "an analog thereof, or a functionally equivalent ligand." Thus, there is no basis for a rejection of GH based on use of GPE. Applicants are not claiming that GPE is "an analog or functionally equivalent ligand" and therefore, there is no overlap in the claims.

Further, as noted above, Applicants submit that Golab does not teach or suggest a neuroprotective role of GH. Rather, Applicants submit that at best, Golab might provide an "invitation to experiment" to see if GH might be a neuroprotective agent. This standard "obvious to try" has been rejected by the courts and is not the proper standard of obviousness. Thus, Golab cannot provide a grounds for obviousness of the instant claims. Rather, Applicants submit that the instant rejection is based on impermissible hindsight reconstruction based on Applicants' own disclosure. Such hindsight reconstruction has been rejected by the courts and is not the proper standard of obviousness.

Finally, the 906 patent discloses the use of a completely different compound, GPE, as a neuroprotective agent. The Examiner has not provided a "reasoned statement" supporting the idea that successful use of GPE as a neuroprotective agent as in the 906 patent, would be viewed by one of ordinary skill in the art as teaching that GH would also be neuroprotective without undue experimentation with a reasonable likelihood of success.

Conclusion

In light of the above, it is respectfully submitted that all of the claims now pending in the subject patent application should be allowable, and a Notice of Allowance is requested. The Examiner is respectfully requested to telephone the undersigned if he can assist in any way in expediting issuance of a patent.

Enclosed is a PETITION FOR EXTENSION OF TIME UNDER 37 C.F.R. § 1.136 for extending the time to respond up to and including November 5, 2006.

Please note the change of Attorney Docket Number. The new docket number is

NRNZ-01006 US0 DBB.

Also, please note change in correspondence Address. The new address is:

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The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 06-1325 for any matter in connection with this response, including any fee for extension of time, which may be required.

Respectfully submitted,

Date: October 20, 2006

By: D. Benjamin Borson

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